

## REMARKS

Claims 1, 3, 6, 27-37 are now presented. Claims 1 and 35 are independent claims. The remaining claims are withdrawn or cancelled as noted.

The previously pending claims 1, 4-6, 29-30 were rejected as being anticipated by Tatsuzo (JP 02311406) entitled "Root Canal Filling Material Composition". The Examiner provided an English abstract. The Examiner indicated a full translation had been ordered but not yet provided. Claims 2, 3 and 26-28 were rejected as unpatentable pursuant to 35 U.S.C. § 103 as being unpatentable over the combination of Tatsuzo in view of Mandal which is believed to be European publication No. 0520690 A2 in the name of applicant Nitta Gelatin Inc. Applicant will refer to the reference hereinafter as the Nitta '690 reference. Applicant traverses the objections as set forth.

Briefly, the invention comprises a unique composition of matter which is especially useful for dental restoration and bone implants. Unique utility is associated with two important benefits associated with the composition; namely, a quick hardening time of the composition and high strength of the hardened composition. An important feature of the composition is the fact that it is a non-aqueous combination of a powdered calcium compound in the form of powder particles combined with a non-toxic, non-aqueous, water miscible liquid and a gelling agent and further a carboxylic acid selected from a specific group of such acids.

A feature of uniqueness of the composition is its non-aqueous nature enabling the composition to be prepared and maintained in a non-aqueous environment available for use as needed. When needed, the addition of an aqueous medium enables adequately quick setting time of the material as a restorable repair material having significantly improved strength characteristics. Among the important aspects of the combination is the inclusion of a gelling agent. The gelling agent precludes wet field washout of the compound in situ. Another important feature of the invention is the recognition that the bone repair or canal filling composition is principally a calcium precursor to hydroxy appetite (HA) and thus is dependent upon multiple calcium

compounds not merely calcium phosphate compounds. The formation of a calcium carboxyl ate complex or salt thus is a feature of the invention. As a further feature of the invention the particle size for the solid materials, namely, the powder particles, is considered very important in determining the hardening times of the material which is desirably less than thirty five minutes, e.g. in the range of ten to 35 minutes. The hardening time is especially important when performing dental or bone restoration techniques. Further the diametral tensile strength as shown in Table 3 of the application is significant and, particularly with respect to bone restoration, an important aspect of the invention.

The Tatsuzo '406 reference is different in numerous aspects. Tatsuzo does not use a gelling agent which is recognized by applicants as an important feature to prevent wet field washout, an aspect particularly important with respect to bone defect repair. Particle size is an important factor inasmuch as the hardening times are dependent upon particle size as discovered by applicants in the context of the composition of the invention. The table in the Tatsuzo reference is understood to report hardening times in range of 2.0 to 8.5 hours indicating clearly a difference in kind of the invention of Tatsuzo relative to the presently claimed invention. Additional Tatsuzo, which is designed for tooth root canal repair, reports no data with respect to tensile strength and must be presumed to have a lesser strength inasmuch as Tatsuzo teaches the use only for root canal filling which is known to typically be directed to strengths that are much lesser than the strengths required for bone restoration.

Turning now to the Nitta '690 reference it will be recognized that the composition taught in that reference is directed to an aqueous combination of materials (see page 3, line 35 et seq.) As taught at page 6 of the reference the materials are combined and constitute an aqueous combination rather than a premixed non-aqueous combination of materials as set forth in the present claims. As such it would be counterintuitive to utilize the aqueous combination of materials set forth in the Nitta '690 reference with the non-aqueous combination of the Tatsuzo reference.

As set forth in Tables 2 and 3 of the Nitta '690 reference it will be noted that all of the examples are directed to an aqueous system where component materials are

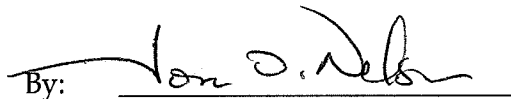
combined and mixed and then apparently utilized for repair purposes. This is precisely the protocol which the present invention avoids. The present invention premixes the non-aqueous components for a repair composition and the mere addition of water enables it effective use. By contrast, in Nitta '690 the materials which are combined comprise a powder and an aqueous solution which includes a secondary material namely a phosphate and organic acid ions. The system involved thus is significantly different from that of the present invention.

Further, it does not appear that the Nitta '690 reference utilizes a gelling agent with respect to the non-aqueous premix material which the subject matter of the present claims. As a consequence not only are the methodology and utilization of the prior art significantly different, but also the materials involved are somewhat different.

For the foregoing reasons therefore, the reference does not teach, disclose or suggest the non-aqueous system set forth in the claims as amended of the present application. Reconsideration thereof and passage to allowance is earnestly solicited.

Respectfully submitted,

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